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UNITED STATES PATENT APPLICATION FOR:

A PARASITICIDAL FORMULATION FOR ANIMALS

INVENTOR:

Richard Mihalik

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A PARASITICIDAL FORMULATION FOR ANIMALS
STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR
DEVELOPMENT

Not applicable.

5 CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. Patent Application Serial No. 09/723,846, filed on November 28, 2000, which is a Continuation of U.S. Patent Application Serial No. 09/573,513, filed on May 18, 2000, which is now issued as U.S. Patent No. 6,207,179, all of which are hereby incorporated herein by reference.

10 BACKGROUND OF THE INVENTION

The present invention relates to a formulation for treating, controlling and preventing parasitic worm infestations and a method for making the formulation. More specifically, the present invention relates to a combination roundworm and tapeworm parasiticide for use in horses and household pets.

15 Several types of parasites, including cestodes, nematodes and obligate parasitic insects, particularly flies, commonly plague horses, dogs and cats. Cestodes are flatworms and include, for example, tapeworms, while nematodes are roundworms. Avermectins and milbemycins are nematocidal agents commonly used in the treatment and control of parasitic roundworm infestations in equines, including domestic horses, donkeys, mules and zebras, as
20 well as in companion animals, namely cats and dogs. These agents are also effective against obligate parasitic flies. Contrary to popular belief among animal owners, however, these agents are ineffective against tapeworm infestations. Rather, tapeworm infestations must be controlled and treated by a cestocidal agent.

Studies have shown that misinformation about tapeworm treatment and control is common among horse owners. Many horse owners evidently believe that ivermectin, an avermectin used for treating and controlling roundworm infestations, is effective in controlling tapeworm infestations as well. This misinformation may account for a rise in the prevalence of 5 certain tapeworms. A particular equine tapeworm whose prevalence is on the rise is *Anoplocephala perfoliata*.

Tapeworms are pervasive parasites that appear to infect at least half of all mature horses. Post-mortem studies have shown that, in general, at least 50% of mature horses in many populations are infected with *A. perfoliata*. *A. perfoliata* is a type of tapeworm that can infect 10 all types of equine animals. Adult *A. perfoliata* attach to the posterior regions of the equine intestinal tract. The highest concentration is in the cecal wall but a fair amount attach to the terminal ilium and ventral colon as well. The greatest concentration of *A. perfoliata*, and thus the greatest associated damage, occurs at the ileocecal junction. *A. perfoliata* infestation increases the incidence of spasmodic colon and ileal impaction in horses. Tapeworms also have 15 been implicated as a cause of cecal and ileocecal intussusceptions in young horses. The latter conditions are potentially fatal and can be remedied only by complicated and expensive abdominal surgery.

There are only a few classes of drugs which are effective in the treatment, control and prevention of tapeworm infestations. Among these classes are praziquantel, pyrantel and 20 morantel compounds. Parasiticidal formulations have been disclosed which contain praziquantel combined with a variety of roundworm controlling agents. One such formulation is disclosed in U.S. Patent No. 5,824,653 to Beuvry et al. The compounds which result from these combinations, however, may be dangerous as praziquantel has been shown to be toxic at levels

other than low dosages. Additionally, praziquantel purportedly is bitter to taste making it unpalatable and thus undesirable in ingestable formulations, for example, pastes.

Pyrantel and morantel compounds are currently believed by those skilled in the art to offer an inadequate substitute to praziquantel in the treatment and control of tapeworm infestations. Pyrantel salts generally either are only partially effective against tapeworms at their label dosages (e.g., pyrantel pamoate) or must be administered in daily regimes (e.g., pyrantel tartrate). Further, pyrantel pamoate offers a low suspended solids content when in paste form, the highest percentage encountered being about 43.95% weight per weight (w/w). A paste with a low suspended solids content contains less active ingredient per unit than a paste with a higher suspended solids content. Therefore, a higher volume of paste must be delivered to the animal in order to achieve the same therapeutic effect.

Accordingly, there remains a need in the veterinary industry for a combination parasiticidal formulation containing both a cestocidal agent and an agent effective against nematodes and obligate parasitic flies that is less toxic than formulations containing praziquantel. Further, a palatable combination parasiticide is needed for administration in ingestable forms. The primary objective of this invention is to meet these needs.

SUMMARY OF THE INVENTION

According to the present invention, the foregoing and other objects are achieved by a parasiticidal formulation that includes a higher content of cestocidal agent than was foreseen as being possible. The formulation preferably includes a mixture of an edible non-aqueous liquid, a thickening agent, an agent effective against nematodes and an agent effective against cestodes, wherein the cestocidal agent is pyrantel, morantel, any salt thereof, or any combination thereof. Another aspect of the present invention is a method of making this parasiticidal formulation. This method includes mixing the above-mentioned components. A further aspect

of the present invention is a method for administering the parasiticidal formulation of the present invention to an animal. This method of administration includes providing the parasiticidal formulation described above in the form of a paste and administering it to an animal for ingestion.

5 Objects of the invention, together with the advantages and novel features appurtenant thereto, will be set forth in part in the description which follows, and in part will become apparent to those skilled in the art upon examination of the following, or may be learned from the practice of the invention. The objects and advantages of the invention may be realized and attained by means of the instrumentalities and combinations particularly pointed out in the
10 appended claims.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The parasiticidal formulation of the present invention is an effective ingestable formulation for the treatment and control of cestode and nematode infestations in equine and companion animals. Such animals include, but are not limited to, horses, donkeys, mules,
15 zebras, dogs and cats. The formulation includes an edible, non-aqueous liquid, a thickening agent, and a cestocidal agent for treating and controlling roundworm infestations and for treating and controlling tapeworm infestations.

The cestocidal agent of the present invention includes pyrantel, morantel, any salt of pyrantel or morantel, or any combination thereof. These compounds offer advantages over
20 praziquantel in the control and treatment of tapeworm infestations in that they have a higher dosage safety margin than praziquantel. Pyrantel pamoate, a salt of pyrantel, for example, should present little to no adverse reaction when ingested by horses in a concentration equivalent to two to five times the label recommended dosage. Further, pyrantels are desirable because horse owners are familiar with this group of compounds. Additionally, pyrantel and morantel are

more palatable than praziquantel as these compounds do not share the bitter taste associated with praziquantel.

Preferably, the cestocidal agent of the present invention is a salt of pyrantel.

Pyrantel salts that may be used in the formulation of the present invention include, but are not

5 limited to, pyrantel pamoate, pyrantel tartrate or any combination thereof. Preferably, the cestocidal agent of the present invention is pyrantel pamoate. Pyrantel pamoate, at sufficiently high dosages, eliminates and controls infestations by a variety of tapeworms, including *Anoplocephala perfoliata*.

Pyrantel pamoate usually is classified as a nematocidal agent rather than a
10 cestocidal agent at its recommended label dosage of about 6.6 milligrams per kilogram of animal. At this dosage, pyrantel pamoate has only partial activity in the treatment and control of tapeworm infestations. Effectiveness percentages from about 65% to 100% against cestode infestations have been shown with paste formulations, the average being about 85% efficacy. However, at about twice the label recommended dosage or higher, pyrantel pamoate exhibits
15 tapeworm controlling activity unattainable by many cestocidal compounds at any dosage. It has been observed that at an elevated dosage of about two times the label recommended dosage, or about 13.2 milligrams per kilogram of animal, pyrantel pamoate exhibits between about 93% and 97.8% efficacy in horses infected with *A. perfoliata*. At an elevated dosage of about three times the label recommended dosage, or about 19.8 milligrams per kilogram of animal, pyrantel
20 pamoate is about 100% effective in treating cestode infestations. Consequently, the parasiticidal formulation of the present invention includes concentrations of pyrantel pamoate at about two to three times the dosage recommended for treatment and control of roundworm infestations.

When the cestocidal agent chosen is pyrantel pamoate, the formulation of the present invention preferably may include about 40-75% w/w pyrantel pamoate (a total of about 14-26% w/w pyrantel in the formulation). More preferably, the formulation of the present invention may include about 50-65% w/w pyrantel pamoate (a total of about 17-23% w/w pyrantel in the formulation). Formulations containing other cestocidal agents besides pyrantel pamoate are also contemplated by this invention, as discussed above. If a different pyrantel compound is used, preferably the formulation would contain pyrantel in an amount similar to the amounts discussed above.

As noted above, at elevated dosages, pyrantel pamoate serves both as a nemotocidal agent and a cestocidal agent. Additional agents which are effective against nematodes and obligate parasitic flies that may be used in the formulation of the present invention include, but are not limited to, avermectins, milbemycins, any derivative thereof, or any combination thereof. Avermectins that may be used in the formulation of the present invention include, but are not limited to, abamectin, doramectin, eprinomectin, ivermectin, moxidectin, selamectin, or any combination thereof. These agents are most effective when substantially dissolved in solution, i.e., when at least about 90% of the agent present is dissolved. Thus, it is preferred that these agents be combined with a solvent before being administered to an animal.

When using ivermectin and pyrantel pamoate in combination, the parasiticidal formulation of the present invention preferably may include about 0.2-1.0% w/w ivermectin and about 45-65% w/w pyrantel pamoate. More preferably, the formulation of the present invention may include about 0.2-0.5% w/w ivermectin and about 50-60% w/w pyrantel pamoate.

The edible, non-aqueous liquid that may be used in the formulation of the present invention includes, but is not limited to, edible glycol polymers, edible oils, or any combination thereof. Edible glycol polymers that may be used in the formulation of the present invention include, but are not limited to, propylene glycol, polyethylene glycol, glycerine (glycerol),
5 glycerol formal, or any combination thereof. Edible oils that may be used in the formulation of the present invention include, but are not limited to, Arachis oil (peanut oil), polyoxyl castor oils, soybean oil, or any combination thereof. Preferably, the edible, non-aqueous liquid is propylene glycol.

The formulation of the present invention preferably may include a total of about
10 40-50% w/w edible, non-aqueous liquid. More preferably, the formulation of the present invention may include about 42-46% w/w edible, non-aqueous liquid.

The thickening agent that may be used in the formulation of the present invention includes, but is not limited to, carbomers, cornstarch, polyethylene, polyvinylpyrrolidones, edible clay, xanthan gum, or any combination thereof. Preferably, the thickening agents are a carbomer
15 and xanthan gum. A suitable carbomer is Carbomer 974P manufactured by B.F. Goodrich. The formulation of the present invention preferably may include about 0.01-1.0% w/w thickening agent. More preferably, the formulation of the present invention may include about 0.09-.65% w/w thickening agent.

The formulation of the present invention allows for higher suspended solids
20 content for some cestocidal agents than was foreseen as being possible from the prior art. For example, the formulation of the present invention allows for a paste containing pyrantel pamoate having a suspended solids content of up to about 70% w/w, with a preferred concentration of about 54.13% w/w. The highest concentration previously encountered in a paste containing

pyrantel was about 43.95% w/w. The higher suspended solids content allows for a significantly smaller volume of paste to be administered, making it easier to deliver higher dosages of pyrantel than when previously available formulations are used.

The parasiticidal formulation of the present invention may be administered either
5 to treat infected animals or to prevent infestations in non-infected animals. Preferably, the formulation is administered once per month.

A number of optional ingredients may be added to enhance certain properties of the formulation. One such optional ingredient is a preservative which acts to preserve both parasiticidal agents in the physical state in which they are most effective. Preservatives that may
10 be used in the formulation of the present invention include, but are not limited to, methylparaben, propylparaben, or any combination thereof. Preferably, the formulation of the present invention includes a combination of methylparaben and propylparaben in a ratio of approximately 10:1 respectively. If a combination of methylparaben and propylparaben is chosen as a preservative for the formulation, the parasiticidal formulation of the present invention preferably may include
15 about 0.15-0.25% w/w methylparaben and about 0.015-0.025% w/w propylparaben. More preferably, the parasiticidal formulation of the present invention may include about 0.18% w/w methylparaben and about 0.02% w/w propylparaben.

Another optional ingredient that may be included in the formulation of the present invention is an additional solvent. Preferably this solvent is water. Water may be present in a
20 concentration ranging from about 0-10% w/w depending upon the concentration of edible, non-aqueous liquid used.

One preferred formulation of the present invention includes pyrantel pamoate, ivermectin, xanthan gum, carbomer, methylparaben, propylparaben and propylene glycol.

Another preferred formulation of the present invention includes pyrantel pamoate, ivermectin, xanthan gum, carbomer and propylene glycol. A highly preferred formulation of the present invention which includes a preservative is described in Example 1. A highly preferred formulation of the present invention which does not include a preservative is described in

5 Example 2.

One parasiticidal formulation of the present invention is made by combining an edible non-aqueous liquid, a thickening agent, an agent effective against nematodes and obligate parasitic flies and a cestocidal agent to form a mixture. The order in which components are added in making the formulation is not critical. The formulation may optionally be heated to

10 between about 60° and 80°C, continuously or intermittently, during its preparation. This process can be scaled to make any desired quantity of the formulation.

One preferred method of making a parasiticidal formulation of the present invention includes placing a quantity of edible, non-aqueous liquid in a vessel and warming it to about 70°C. Next, a quantity of an agent effective against nematodes and obligate parasitic flies

15 is added, and the resulting solution is cooled to room temperature. The cestocidal agent is then added and mixed with the solution for an effective period of time. The cestocidal agent will not dissolve into solution but instead will remain generally suspended throughout, i.e., less than about 10% will dissolve. A thickening agent is then added and mixed into the solution until it dissolves substantially, i.e., until at least 90% of the thickening agent present is dissolved.

20 Optionally, a preservative then may be added and mixed into the solution until substantially dissolved, i.e., until at least 90% of the preservative present is dissolved.

Preferably, the parasiticidal formulation of the present invention is administered as a paste formulation to any equine or companion animal. It is particularly useful for domestic

horses, donkeys, mules, zebras, cats and dogs. Preferably, the paste is ingested by the animal and is administered in a dosage of about 65-75 milligrams per kilogram of animal once per month.

The following are examples of various parasiticidal formulations and methods of

- 5 making these formulations that are within the scope of this invention. These examples are not meant in any way to limit the scope of this invention.

EXAMPLE 1

Propylene glycol, in a quantity amounting to 44.17% w/w of the final formulation, was added to a vessel and warmed to 70°C. Agitation began. With continued 10 agitation, a quantity of ivermectin amounting to 0.29% w/w of the final formulation was added to the propylene glycol and mixed with it until all of the ivermectin substantially dissolved. The resulting solution was then cooled to room temperature. A quantity of pyrantel pamoate amounting to 55.14% w/w of the final formulation (19.13% w/w of final formulation as pyrantel) was then added and mixed with the solution. The pyrantel pamoate did not dissolve in the 15 solution but instead remained generally suspended throughout. Next, a quantity of xanthan gum amounting to 0.18% w/w of the final formulation was added to the mixture. With continued agitation, Carbomer 974P was added to the mixture in a quantity amounting to 0.02% w/w of the final formulation. Subsequently, methylparaben, in a quantity amounting to 0.18% w/w of the final formulation, was added to the mixture, followed by a quantity of propylparaben amounting 20 to 0.02% w/w of the final formulation. The resulting formulation is within the scope of the present invention and includes two parasiticidal agents, each targeting different species of parasites.

EXAMPLE 2

Propylene glycol, in a quantity amounting to 44.37% w/w of the final formulation, was added to a vessel and warmed to 70°C. Agitation began. With continued agitation, a quantity of ivermectin amounting to 0.29% w/w of the final formulation was added 5 to the propylene glycol and mixed with it until all of the ivermectin substantially dissolved. The resulting solution was then cooled to room temperature. A quantity of pyrantel pamoate amounting to 55.14% w/w of the final formulation (19.13% w/w of final formulation as pyrantel) was then added and mixed with the solution. The pyrantel pamoate did not dissolve in the solution but instead remained generally suspended throughout. With continued agitation, a 10 quantity of xanthan gum amounting to 0.18% w/w of the final formulation was added to the mixture. Subsequently, carbomer 974P was added to the mixture in a quantity amounting to 0.02% w/w of the final formulation. The resulting formulation is within the scope of the present invention and includes two parasiticidal agents, each targeting different species of parasites.

15 EXAMPLE 3

Propylene glycol, in a quantity amounting to 30% w/w of the final formulation, was added to a vessel and warmed to 70°C. Agitation began. With continued agitation, water in a quantity amounting to 7.285% w/w of the final formulation, was added to the propylene glycol to form a solution. Next, a quantity of ivermectin amounting to 0.325% w/w of the final 20 formulation was added to the solution and mixed with it until all of the ivermectin substantially dissolved. The resulting solution was then cooled to room temperature. A quantity of pyrantel pamoate amounting to 61.74% w/w of the final formulation (21.42% w/w of final formulation as pyrantel) was then added and mixed with the solution. The pyrantel pamoate did not dissolve in the solution but instead remained generally suspended throughout. Lastly, a quantity of xanthan

gum amounting to 0.65% w/w of the final formulation was added to the mixture. The resulting formulation is within the scope of the present invention and includes two parasiticidal agents, each targeting different species of parasites.

EXAMPLE 4

5 Propylene glycol, in a quantity amounting to 28% w/w of the final formulation, was added to a vessel and warmed to 70°C. Agitation began. With continued agitation, water, in a quantity amounting to 9.285% w/w of the final formulation, was added to the propylene glycol to form a solution. Next, ivermectin amounting to 0.325% w/w of the final formulation was added to the solution and mixed with it until all of the ivermectin substantially dissolved. The 10 resulting solution was then cooled to room temperature. A quantity of pyrantel pamoate amounting to 61.74% w/w of the final formulation (21.42% w/w of final formulation as pyrantel) was then added and mixed with the solution. The pyrantel pamoate did not dissolve in the solution but instead remained generally suspended throughout. Lastly, a quantity of xanthan gum amounting to 0.65% w/w of the final formulation was added to the mixture. The resulting 15 formulation is within the scope of the present invention and includes two parasiticidal agents, each targeting different species of parasites.

EXAMPLE 5

Propylene glycol, in a quantity amounting to 32.0% w/w of the final formulation, was added to a vessel and warmed to 70°C. Agitation began. With continued agitation, water, in 20 a quantity amounting to 5.285% w/w of the final formulation, was added to the propylene glycol to form a solution. Next, ivermectin amounting to 0.325% w/w of the final formulation was added to the solution and mixed with it until all of the ivermectin substantially dissolved. The resulting solution was then cooled to room temperature. A quantity of pyrantel pamoate amounting to 61.74% w/w of the final formulation (21.42% w/w of final formulation as pyrantel)

was then added and mixed with the solution. The pyrantel pamoate did not dissolve in the solution but instead remained generally suspended throughout. Lastly, a quantity of xanthan gum amounting to 0.65% w/w of the final formulation was added to the mixture. The resulting formulation is within the scope of the present invention and includes two parasiticidal agents,
5 each targeting different species of parasites.

EXAMPLE 6

Propylene glycol, in a quantity amounting to 37.836% w/w of the final formulation, was added to a vessel and warmed to 70°C. Agitation began. With continued agitation, water, in a quantity amounting to 7.0% w/w of the final formulation, was added to the
10 propylene glycol to form a solution. Next, ivermectin amounting to 0.284% w/w of the final formulation was added to the solution and mixed with it until all of the ivermectin substantially dissolved. The resulting solution was then cooled to room temperature. A quantity of pyrantel pamoate amounting to 54.03% w/w of the final formulation (18.75% w/w of final formulation as pyrantel) was then added and mixed with the solution. The pyrantel pamoate did not dissolve in
15 the solution but instead remained generally suspended throughout. With continued agitation, a quantity of xanthan gum amounting to 0.65% w/w of the final formulation was added to the mixture. Lastly, Carbomer 974P was added to the mixture in a quantity amounting to 0.02% w/w of the final formulation. The resulting formulation is within the scope of the present
20 invention and includes two parasiticidal agents, each targeting different species of parasites.

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EXAMPLE 7

Propylene glycol, in a quantity amounting to 44.806% w/w of the final formulation, was added to a vessel and warmed to 70°C. Agitation began. With continued agitation, water, in a quantity amounting to 0.48% w/w of the final formulation, was added to the propylene glycol to form a solution. Next, ivermectin amounting to 0.284% w/w of the final

formulation was added to the solution and mixed with it until all of the ivermectin substantially dissolved. The resulting solution was then cooled to room temperature. With continued agitation, a quantity of pyrantel pamoate amounting to 54.03% w/w of the final formulation (18.75% w/w of final formulation as pyrantel) was then added and mixed with the solution. The
5 pyrantel pamoate did not dissolve in the solution but instead remained generally suspended throughout. Next, a quantity of xanthan gum amounting to 0.2% w/w of the final formulation was added to the mixture. Lastly, Carbomer 974P was added to the mixture in a quantity amounting to 0.2% w/w of the final formulation. The resulting formulation is within the scope of the present invention and includes two parasiticidal agents, each targeting different species of
10 parasites.

EXAMPLE 8

Propylene glycol, in a quantity amounting to 43.4% w/w of the final formulation, was added to a vessel and warmed to 70°C. Agitation began. With continued agitation, a quantity of ivermectin amounting to 0.275% w/w of the final formulation was added to the
15 propylene glycol and mixed with it until all of the ivermectin substantially dissolved. The resulting solution was then cooled to room temperature. A quantity of pyrantel pamoate amounting to 56.17% w/w of the final formulation (19.49% w/w of final formulation as pyrantel) was then added and mixed with the solution. The pyrantel pamoate did not dissolve in the solution but instead remained generally suspended throughout. With continued agitation, a
20 quantity of xanthan gum amounting to 0.097% w/w of the final formulation was added to the mixture. Lastly, Carbomer 974P was added to the mixture in a quantity amounting to 0.097% w/w of the final formulation. The resulting formulation is within the scope of the present invention and includes two parasiticidal agents, each targeting different species of parasites.

EXAMPLE 9

Propylene glycol, in a quantity amounting to 44.14% w/w of the final formulation, was added to a vessel and warmed to 70°C. Agitation began. With continued agitation, a quantity of ivermectin amounting to 0.29% w/w of the final formulation was added 5 to the propylene glycol and mixed with it until all of the ivermectin substantially dissolved. The resulting solution was then cooled to room temperature. A quantity of pyrantel pamoate amounting to 55.17% w/w of the final formulation (19.14% w/w of final formulation as pyrantel) was then added and mixed with the solution. The pyrantel pamoate did not dissolve in the solution but instead remained generally suspended throughout. Next, a quantity of xanthan gum 10 amounting to 0.1% w/w of the final formulation was added to the mixture. With continued agitation, Carbomer 974P was added to the mixture in a quantity amounting to 0.1% w/w of the final formulation. Subsequently, methylparaben, in a quantity amounting to 0.18% w/w of the final formulation, was added to the mixture, followed by a quantity of propylparaben amounting 15 to 0.02% w/w of the final formulation. The resulting formulation is within the scope of the present invention and includes two parasiticidal agents, each targeting different species of parasites.

EXAMPLE 10

Propylene glycol, in a quantity amounting to 49.705% w/w of the final formulation, was added to a vessel and warmed to 70°C. Agitation began. With continued 20 agitation, a quantity of ivermectin amounting to 0.235% w/w of the final formulation was added to the propylene glycol and mixed with it until all of the ivermectin substantially dissolved. The resulting solution was then cooled to room temperature. A quantity of pyrantel pamoate amounting to 49.7% w/w of the final formulation (17.25% w/w of final formulation as pyrantel) was then added and mixed with the solution. The pyrantel pamoate did not dissolve in the

solution but instead remained generally suspended throughout. Next, a quantity of xanthan gum amounting to 0.135% w/w of the final formulation was added to the mixture. With continued agitation, Carbomer 974P was added to the mixture in a quantity amounting to 0.045% w/w of the final formulation. Subsequently, methylparaben, in a quantity amounting to 0.162% w/w of the final formulation, was added to the mixture, followed by a quantity of propylparaben amounting to 0.018% w/w of the final formulation. The resulting formulation is within the scope of the present invention and includes two parasiticidal agents, each targeting different species of parasites.

EXAMPLE 11

Propylene glycol, in a quantity amounting to 38.199% w/w of the final formulation, was added to a vessel and warmed to 70°C. Agitation began. With continued agitation, a quantity of sterile water in a quantity amounting to 6.0% w/w of the final formulation was added to the propylene glycol to form a solution. Next, ivermectin amounting to 0.261% w/w of the final formulation was added to the solution and mixed with it until all of the ivermectin substantially dissolved. The resulting solution was then cooled to room temperature. A quantity of pyrantel pamoate amounting to 55.14% w/w of the final formulation (19.13% w/w of final formulation as pyrantel) was then added and mixed with the solution. The pyrantel pamoate did not dissolve in the solution but instead remained generally suspended throughout. With continued agitation, a quantity of xanthan gum amounting to 0.1% w/w of the final formulation was added to the mixture. With continued agitation, a quantity of Carbomer 974P was added to the mixture in a quantity amounting to 0.1% w/w of the final formulation. Lastly, methylparaben, in a quantity amounting to 0.18% w/w of the final formulation, was added to the mixture, followed by a quantity of propylparaben amounting to 0.02% w/w of the final

formulation. The resulting formulation is within the scope of the present invention and includes two parasiticidal agents, each targeting different species of parasites.

EXAMPLE 12

Propylene glycol, in a quantity amounting to 44.19% w/w of the final formulation, was added to a vessel and warmed to 70°C. Agitation began. With continued agitation, a quantity of ivermectin amounting to 0.261% w/w of the final formulation was added to the propylene glycol and mixed with it until all of the ivermectin substantially dissolved. The resulting solution was then cooled to room temperature. A quantity of pyrantel pamoate amounting to 55.14% w/w of the final formulation (19.13% w/w of final formulation as pyrantel) was then added and mixed with the solution. The pyrantel pamoate did not dissolve in the solution but instead remained generally suspended throughout. Next, a quantity of xanthan gum amounting to 0.15% w/w of the final formulation was added to the mixture. With continued agitation, Carbomer 974P was added to the mixture in a quantity amounting to 0.05% w/w of the final formulation. Lastly, methylparaben, in a quantity amounting to 0.18% w/w of the final formulation, was added to the mixture, followed by a quantity of propylparaben amounting to 0.02% w/w of the final formulation. The resulting formulation is within the scope of the present invention and includes two parasiticidal agents, each targeting different species of parasites.

From the foregoing, it will be seen that this invention is one that is well adapted to attain all the ends and objects hereinabove set forth together with other advantages which are obvious and inherent to the formulation.

It will be understood that certain features and subcombinations are of utility and may be employed without reference to other features and subcombinations. This is contemplated by and is within the scope of the claims.

Since many possible embodiments may be made of the invention without departing from the scope thereof, it is to be understood that all matter herein set forth is to be interpreted as illustrative and not in a limiting sense.